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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,477	06/04/2002	Edmond D. Roussel	HER0050	1783

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/031,477	<b>Applicant(s)</b> ROUSSEL ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the recitation of “propionibacteria”. The correct term is *Propionibacterium*.

In keeping with scientific custom, the names of microorganisms should be italicized or underlined.

The amendment filed 10/18/04 is acknowledged. Claims 10-37 are being considered on the merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 27 are vague, indefinite and confusing in that the nature of the food supplement or product provide is not delineated with sufficient clarity. All the method requires is that the product be provided “based upon the choice of propionibacteria able to...” in the preamble. There is no indication as to the nature of the composition or the actual content of active ingredients therein. The step b) requires merely that *Propionibacterium* be “utilized” or “incorporated” in the product. The extent of “utilization” or “incorporation” is not set forth.

Claims 10 and 27 vague and indefinite in the recitation of a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim,

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and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation “short chain fatty acids”, and the claim also recites “propionic acid and/or propionates which is the narrower statement of the range/limitation.

Claim 10 is vague and indefinite in the multiple recitations of “predetermined” regarding the process parameters. For example, the concentration of bile required to provide a “bile environment” is not claim designated. In addition, there is no indication of what constitutes a “selected level of yield” and the extent of “above” is not ascertainable.

Claim 12 is confusing in that “capable of favouring” does not constitute a positive limitation of the claim.

Claims 12-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 14 fails to find proper antecedent basis for “the colonocytes”.

The recitation of “it can be utilized in a manner to be protected at least partially from stomach acidity” in claim 17 does not constitute a positive limitation of the claim.

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 21 is confusing in the recitation of “lactic acid and/or bifid bacteria”. The genus name is *Bifidobacterium*. It is also noted that these bacteria are considered to be lactic acid bacteria.

Claim 22 fails to find clear antecedent basis in claim 10 for “said selection”. Item iii. is directed to “selecting as said selected strain...”

Claim 23 fails to find clear antecedent basis in claim 10 for the selection process intended. Item iii. is directed to “selecting as said selected strain...”.

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Claim 25 is vague and indefinite in that it is uncertain how steps (a)-(g) are to correlate with steps i.-iii. of claim 10. In other words, it cannot be readily determined at which stage of the identification process of claim 10 are the process steps of claim 25 inserted.

In claim 27 it is unclear what constitutes “taking up in YEL” medium.

Claim 27 is confusing in that the correlation between steps i.-vii. and b)-f). is not clearly set forth. The origin of the strains of b) is not ascertainable.

Claim 27 is vague and indefinite in the multiple recitations of “predetermined” in steps c) and d) regarding the process parameters. For example, the concentration of bile required to provide a “bile environment” is not claim designated.

Claim 28 is vague indefinite and confusing in the recitation “non very autolytic”. It is uncertain how this property is to be assessed in this context.

Claim 28 is vague and indefinite in the proviso “ and if the need arises acetic acid and/or acetate”. It is uncertain how this need is measured and/or met. In addition, it cannot be readily determined whether the propionic acid and/or propionate is synthesized in the colon in this context.

Claim 29 is vague and indefinite in the recitation of a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation “mineral substances”, and the claim also recites “calcium and/or iron and/or zinc and/or magnesium” which is the narrower statement of the range/limitation.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roussel *et al.* (WO 97/19689) taken with Roussel *et al.* (WO 98/27991).

The invention is directed to a method of providing a food supplement by use of propionic acid bacteria which are prepared by a method comprising stressing with bile and which produce propionic acid. These strains also are claimed to produce at least 2 g/l of propionic acid and/or of propionates.

Roussel *et al.* '689 disclose the production of food compositions using propionic acid bacteria. The propionic acid bacteria used have been selected to be resistant to bile at least to some extent. A strain select specifically to be resistant to bile concentrations of 1, 2 and 5 g/l is strain LS 410. See, e.g., page 9, line 18.

The strains are characterized as being not very autolytic and to produce propionic acid at least to some extent, as shown on page 11, paragraph 3.

The reference is silent regarding cultivation of propionic acid bacteria at 30° C in YEL medium containing lactate. However, Roussel '991 disclose cultivation of strains of *Propionibacterium* at 30° C in YEL medium in several rounds of cultivation. See, e.g., page 9, lines 30 et seq.. Inasmuch as the propionic acid bacteria may be provided with lactic acid bacteria, it can be reasonably presumed that at least some lactate is present during the culturing process. In addition, these strains of interest are known to produce propionic and acetic acid (Roussel '689, page 2, lines 33-35). This reference also discloses individual fractions of dry or hydrated preparations presented in the form of fractions containing at least 10<sup>8</sup> cells (page 5).

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These compositions are gastroresistant. The results discussed at page 7 of Roussel '689 strongly suggest that the propionic acid bacteria have properties of adhesion on colonocytes since the microorganisms reside in the colon. The propionic acid bacteria compositions contain lactic acid and/or *Bifidobacterium*.

Moreover, the "identification" process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering. It is also emphasized that it is not apparent that the food supplement provided as the product in the instant process differs in any way from the food supplement provided in the Roussel references, since the claims require merely that *Propionibacterium* be "utilized" or "incorporated" in the product. The extent of "utilization" or "incorporation" is not set forth.

In addition, it is noted that the *Propionibacterium* cells used in the process of providing a food supplement are claimed a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of providing a food supplement of Roussel *et al.* '689 by providing a food composition utilizing *Propionibacterium* using the specific culture media as suggested by Roussel *et al.* '991 in order to obtain a food composition containing propionic acid bacteria having a high production ability of propionic acid for the expected benefit of promoting the growth of lactic acid bacteria or *Bifidobacterium* in the colon and achieving the concomitant protective effects of probiotic cultures.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

#### ***Response to Arguments***

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Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that there are unexpected results due to the claimed invention regarding obtaining strains that reach the colon and thus an unexpectedly high output of propionic acid is obtained. However, there is no clear nexus between the results touted and the invention as claimed. The claims as written fail to distinguish over the art cited.

In addition, Applicant has not demonstrated with objective evidence that the food supplement provided differs in any way from the food supplement provided in the references. It is emphasized that the claims only require that *Propionibacterium* strains be "utilized" or "incorporated" in the product. Moreover, the selection steps intended are not delineated with sufficient particularity to conclude that the strains obtained in this manner would reproducibly reach the colon and thus yield unexpectedly high outputs of propionic acid upon ingestion.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx



**IRENE MARX**  
**PRIMARY EXAMINER**